IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

HEALTH CHOICE GROUP, LLC and JAIME GREEN, on behalf of the UNITED STATES OF AMERICA; STATE OF ARKANSAS; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; and STATE OF WASHINGTON,

Plaintiffs/Relators,

v.

BAYER CORPORATION; AMGEN INC.; ONYX PHARMACEUTICALS, INC.; AMERISOURCEBERGEN CORPORATION; and LASH GROUP,

Defendants.

Civil Action No.: 5:17-CV-126-RWS-CMC

RELATORS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT

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Abbreviation	Term
AC	Amended Complaint
AKS	Anti-Kickback Statute
Amerisource	AmerisourceBergen Corporation and Lash Group
Amgen	Amgen Inc. and Onyx Pharmaceuticals, Inc.
DHHS	Department of Health and Human Services
FCA	False Claims Act
Green	Jaime Green
Health Choice	Health Choice Group LLC
MS	Multiple Sclerosis
OIG	Office of the Inspector General
Plaintiff States	The States identified in the caption of this matter
Prescriber	Any physician or Advance Practice Provider authorized to write prescriptions, as well as their employees
Relators	Health Choice Group, LLC and Jaime Green

I. INTRODUCTION

The AC alleges that, with substantial assistance from Amerisource, Bayer and Amgen have engaged in three unlawful schemes to induce Prescribers to prescribe Bayer and Amgen products. Two of these schemes involved the payment of in-kind remuneration to Prescribers in the form of reimbursement support assistance and staffing services. The third scheme involved the payment of cash to so-called "nurse educators" who, while purporting to provide disease-awareness education, were trained and tasked to act as undercover, "white-coated" sales agents for Bayer and Amgen. Each of the three schemes constitutes a violation of the AKS and equivalent statutes enacted by each of the Plaintiff States.

The AC is based on a thorough investigation performed by Health Choice, including interviews with numerous individuals who participated in the schemes, and Green's personal knowledge. The AC pleads ample facts to support Relators' allegations, sufficiently pleads each element of Relators' causes of action, and meets – and, in fact, exceeds – the applicable pleading standards.

Ignoring the AC's particularized allegations and established precedent, Defendants have now moved to dismiss. While it raises numerous arguments, Defendants' motion largely boils down to the notion that, at the pleading stage, Relators should be required to *prove* their claims by, among other things, identifying each detail of Defendants' unlawful scheme and tying each of Defendants' illegal acts to a false claim resulting therefrom. None of Defendants' arguments passes muster, and the motion to dismiss should be denied in its entirety.

II. RELEVANT BACKGROUND

A. The Statutory Background

The AKS makes it unlawful to "offer or pay any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . ." in return for (1)

"referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program"; or (2) "purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1)(A)-(B).

DHHS, the federal agency charged with interpreting the AKS, has consistently maintained that the use of the term "remuneration" in the AKS statute "demonstrate[s] congressional intent to create *a very broadly worded prohibition*," and explained that "remuneration" under the AKS means "*anything of value in any form or manner whatsoever*." 56 Fed. Reg. 35952, 35958 (July 29, 1991) (emphasis added). Over the years, DHHS has been steadfast in affirming the AKS's broad scope.[1] Consistent with DHHS's guidance, courts have consistently recognized that "remuneration," as used in the AKS, means "*anything* of value."[2]

In relevant part, the FCA establishes treble damages liability to the United Sates for any individual or entity that: (1) "knowingly presents, or causes to be presented, a false or fraudulent

[1] *See, e.g.*, *In re Inspector General v. Hanlester Network*, Dkt. Nos. C-186 through C-192, No. C-208, & No. C-213, Decision No. 1275, 1991 WL 634852 (DHHS Sept. 18, 1991) ("The plain meaning of the statutory language, as well as its context, purpose, and history, support a conclusion that a violation occurs whenever an individual or entity knowingly and willfully offers or pays anything of value, in any manner or form, with the intent of exercising influence over a physician's reason or judgment in an effort to cause the referral of program-related business."); OIG Special Fraud Alert: Home Health Fraud, 60 Fed. Reg. 40847, 40848 (Aug. 10, 1995) ("Under the anti-kickback statute, it is illegal to knowingly and willfully solicit, receive, offer or pay anything of value to induce, or in return for, referring, recommending or arranging for the furnishing of any item or service payable by Medicare or Medicaid."); Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518 (Nov. 19, 1999) (noting that the "[s]traightforward and broad" definition of "remuneration" includes "anything of value").

[2] *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 678 (N.D. Ill. 2006) ("Remuneration, for purposes of the AKS, is defined broadly, meaning 'anything of value.'"); *United States v. Shaw*, 106 F. Supp. 2d 103, 114 (D. Mass. 2000) ("Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.") (quotations omitted).

claim for payment or approval"; (2) "knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"; or (3) "conspires to commit a violation of [the foregoing paragraphs]." 31 U.S.C. § 3729(a)(1)(A)-(C).

Each of the Plaintiff States has enacted statutes that parallel the AKS and the FCA. *See* AC ¶¶ 221-375.

Compliance with the AKS and its state-equivalents is required for reimbursement of claims from federal health care programs (*e.g.*, Medicare) and state health care programs (*i.e.* Medicaid). "[A] claim that includes items or services resulting from a violation of . . . [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

B. The Relators

Relator Health Choice is an affiliate of the National Healthcare Analysis Group ("NHAG"), a research organization based in New Jersey. Each year, NHAG representatives conduct hundreds of interviews of participants in the healthcare marketplace – nurses, sales representatives ("sales reps"), office managers, administrators, reimbursement support personnel, etc. – to form an understanding of industry practices. AC ¶ 26.

Relator Green is a nurse based out of Houston, Texas. AC ¶ 27. From approximately November 2015 through April 2017, Green worked as a nurse educator for Adempas, a Bayer product. *Id.* Green performed her work pursuant to a contract between Bayer and Green's then-employer, Ashfield. *Id.*

C. Defendants' AKS violations

The AC spells out three inter-related schemes that constitute violations of the AKS.

Scheme one: free nurse services. In the first scheme (the "Free Nurse" program), Bayer and Amgen offered free nurse education and patient management services to induce Prescribers

to prescribe Bayer and Amgen products over those made by competitors. AC ¶ 92. Bayer and Amgen provided these services through Amerisource nurses. *Id.*

Most Prescribers typically allocate between 10 and 15 minutes to see routine patients. *Id.* ¶ 93. However, patients suffering from particular diseases, such as MS or cancer, often require extra office time, training, and resources to manage their disease. *Id.* For this purpose, to treat patients affected by particular diseases, Prescribers frequently rely on certified nurse educators. *Id.* The cost associated with the use of nurse educators, however, is significant – a nurse educator often commands an annual salary that exceeds $60,000, or an average hourly rate of $40 per hour. *Id.*

Seeking to exploit the need of Prescribers and healthcare organizations and the challenges they face in managing patients affected by chronic diseases, Bayer and Amgen developed a marketing strategy that involves furnishing nurse educators to Prescribers to induce them to prescribe Bayer and Amgen products. *Id.* ¶ 94. The Free Nurse program became a powerful tool in the hands of Bayer and Amgen sales reps: in exchange for prescribing Bayer and Amgen products, Prescribers reduced the time and cost required to treat those patients, freed up time to see other patients, and increased profitability. *Id.* ¶¶ 96-107.

Scheme two: "white coat" marketing by nurse educators. In the second scheme (the "White Coat Marketing" program), Bayer and Amgen paid nurse educators to act as undercover sales agents. *Id.* ¶ 108. Because Prescribers are oftentimes skeptical of drug reps, Bayer and Amgen relied heavily on teams of nurses supplied by Amerisource to promote Bayer and Amgen products. *Id.* ¶ 110. Bayer and Amgen contrived a "disease awareness" program and deployed nurse educators to influence Prescribers and their staff to recommend Bayer and Amgen products. *Id.* ¶ 115. In truth, however, these nurse educators were nothing more than "white-

coated" sales reps: (1) they had received sales training from Bayer and Amgen; (2) they were actively used by Bayer and Amgen to drive sales; (3) they gained access to Prescribers to drive prescriptions; (4) they were expressly tasked to promote Bayer and Amgen products; and (5) they also engaged in direct marketing to patients on behalf of Bayer and Amgen. *Id.* ¶¶ 116-145.

Scheme three: reimbursement support services. In the third scheme, with assistance from Amerisource, Bayer and Amgen offered Prescribers free reimbursement support services in exchange for prescribing Bayer and Amgen products. *Id.* ¶ 146. When a Prescriber receives payment from Medicare or Medicaid programs for so-called "evaluation and management services" (a technical term for an office visit), the payment is intended to compensate the Prescriber for medical care given, as well as various administrative tasks associated with the patient's care. *Id.* ¶¶ 152-53. These administrative tasks include various reimbursement support services such as, among other things, conducting a patient's prescription drug insurance benefit verification, determining if the drug is on the formulary lists and tiers, seeking a coverage determination, determining co-pays and deductibles, managing the process that results in obtaining prior authorizations, and managing the resulting paper trail (collectively, "Support Services"). *Id.* ¶ 153. The costs associated with Support Services are significant. For instance, a 2011 study published in *Health Affairs* found that providers spend an annual average of nearly $83,000 of overhead staff time and costs associated with coverage plan issues. *Id.* at 47 n.28. Despite these enormous administrative costs and expenses, office-based Prescribers are not permitted, under federal or state regulations, to directly charge patients a fee for any of these reimbursement support services. *Id.* ¶ 153.

The AC alleges that, to induce Prescribers to prescribe Bayer and Amgen products, Bayer and Amgen sales reps offered Prescribers a reimbursement support team to manage the

administrative tasks associated with prescribing the drug. *Id.* ¶ 157. Support Services were only made available to Prescribers *if* they prescribed Bayer and Amgen products. *Id.* ¶ 167. Relators' investigation indicates that between 70% and 95% of Prescribers utilized Support Services – resulting in a staggering number of prescriptions for Bayer and Amgen products. *Id.* ¶ 164.

The AC provides extensive details with respect to each of the three schemes, and explains how each has resulted in violations of the AKS.

III. LEGAL STANDARD

"In the Fifth Circuit, motions to dismiss under Rule 12(b)(6) are viewed with disfavor and rarely granted." *OLA, LLC v. Builder Homesite, Inc.*, 661 F. Supp. 2d 668, 672 (E.D. Tex. 2009) (citing *Lormand v. U.S. Unwired, Inc.*, 565 F.3d 228, 232 (5th Cir. 2009)). A complaint need only set forth "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). At the pleading stage, a court must accept all allegations in the complaint as true and construe the complaint liberally in the plaintiff's favor. *Am. Airlines, Inc. v. Travelport Ltd.*, 2012 U.S. Dist. LEXIS 126934, at *9 (N.D. Tex. Aug. 7, 2012) (citing *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1050 (5th Cir. 1982)). To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation and internal quotation marks omitted). This plausibility standard "does not impose a probability requirement at the pleading stage; it simply calls for enough facts to raise a reasonable expectation" of a right to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007).

Although Rule 9(b) of the Federal Rules of Civil Procedure sets a heightened pleading standard for complaints asserting fraud claims, "this requirement 'does not reflect a subscription to fact pleading.'" *United States ex rel. Fisher v. Homeward Residential, Inc.*, 2015 WL

3794530, at *2 (E.D. Tex. June 17, 2015) (citing *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 186 (5th Cir. 2009)). Rule 9(b) requires particularity, but the evaluation of a complaint under this standard "is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim[s] Act." *Grubbs*, 565 F.3d at 190; *United States v. Paramedics Plus LLC*, 2017 WL 4812443, at *3 (E.D. Tex. Oct. 25, 2017). Rule 9(b) does not require a plaintiff to "include[] all the details of any single court-articulated standard." *Id.* at 188.

IV. ARGUMENT

A. The AC Adequately Pleads Relators' FCA Claims

Defendants assert that Relators have failed to adequately plead violations of the FCA. Defendants are mistaken. The AC sets forth facts that, accepted as true, establish each element of an FCA claim in sufficient detail for this stage of the litigation.

1. The AC Adequately Pleads Violations of the AKS

a. The Free Nurse and Support Services Programs Constitute Unlawful Remuneration under the AKS

Defendants assert that the Free Nurse and Support Services programs do not violate the AKS "because each of these services described are limited to the support of one of the Medicines and provide no substantial, independent value to prescribers." MTD at 9. Defendants are mistaken, and neither the OIG guidance nor the case law supports their arguments.

First, the Compliance Program Guidance for Pharmaceutical Manufacturers ("CPG") issued by the OIG unambiguously makes clear that pharmaceutical companies like Bayer and Amgen may run afoul of the AKS if they offer to Prescribers "anything of value." This includes any "service" that would "*eliminate an expense the physician would have otherwise incurred*" or any "service" that is "sold to a physician *at less than fair market value*." 68 Fed. Reg. 23731 §

IIB(2)(b)(B)(1)(b) (emphasis added). The service in question need only meet one of these tests. Here, the services satisfy both. Bayer and Amgen have provided unlawful remuneration to Prescribers because the Free Nurse and Support Services programs (1) eliminate staff and administrative expenses that a Prescriber would have to incur each time it writes a prescription; *and* (2) Bayer and Amgen do not charge the Prescribers fair market value for the benefits they receive under the Free Nurse and Support Services programs.

Defendants' assertion that the OIG has indicated that "'support services . . . tied to support of the purchased products' may not constitute illegal remuneration under the AKS without some additional showing of other 'substantial independent value to the purchaser'" (MTD at 9-10) is incorrect. Indeed, the portion of the CPG guidance Defendants are referencing *does not apply to "prescribing physicians."* Rather, it applies to "*purchasers*" (*e.g.*, hospitals, nursing homes, pharmacies, wholesales).

The distinction OIG drew between "purchasers" and "prescribing physicians" is significant and dispositive here. And, to be sure, there are sound and long-standing policy reasons why OIG treats a drug company's interaction with "purchasers" differently than a drug company's interactions with "prescribing physicians." Purchasers are not typically in a "position to refer, order, or prescribe" items or services to patients. Rather, purchasers essentially warehouse pharmaceutical products. "Prescribing physicians," on the other hand, are in a position of trust with their patients and can and do prescribe drugs to those patients. Unlike a warehouse, the Prescriber *actually decides* which pharmaceutical products will be used during treatment. By imposing additional safeguards on conduct that implicates prescribing physicians or others who are in a position to refer patients for items or services, the AKS ensures that the Government pays only for conflict-free medical care and items or services that are provided in

the best interests of the patient. A kickback eliminates any sound basis for such assurance because it taints prescribing physician's medical decisions with the Prescriber's financial interests. *See, e.g., United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011) (internal quotations omitted).

In the AC, Relators make clear that the Prescribers Bayer and Amgen have targeted with the Free Nurse and Support Services programs are "prescribing physicians," *not* warehouses or entities that themselves purchase the Bayer and Amgen products. Since OIG provided specific guidance for "*prescribing physicians,*" the broad definition of "anything of value" set forth in the CPG's physician section controls; and the definition in the "purchaser" section of the CPG is irrelevant. And because the challenged conduct "eliminate[s] an expense the physician would have otherwise incurred" and provides a valuable service to the physician "at less than fair market value" (indeed, for free), Bayer and Amgen's conduct falls squarely within the prohibition set forth in the CPG.

Even if the "purchaser" guidance set forth in the CPG were to apply, the AC contains ample allegations that establish that the Free Nurse and Support Service programs do in fact provide independent value to the Prescribers. This is because both programs eliminate *substantial* expenses the Prescribers would otherwise have to incur. *See supra* at 3-4 (noting that the Free Nurse program eliminates the need for Prescriber to hire their own staff to provide the services Bayer and Amgen are providing); *id.* at 5-6 (noting that the Support Services program eliminates substantial expenses the Prescribers would otherwise have to incur).

Second, Defendants' reliance on *United States ex rel. Forney v. Medtronic, Inc.*, 2017 WL 2653568 (E.D. Pa. June 19, 2017), is misplaced. That case involved Medtronic's extended warranty product services for *electronic devices* such as "pacemakers, defibrillators, stents," etc.

Id. at *2. The relator alleged that Medtronic's provision of "free surgical support, implant device follow-up that it continued to offer long after device implantation, and free staff to clinics at which Medtronic employees would spend four to eight hours conducting interrogations and other services" constituted unlawful remuneration under the AKS. Using the CPG's guidance for "*purchasers*" – not "prescribing physicians" – the court found the complaint's allegations insufficient because, among other reasons, the relator (1) "failed to allege with the particularity Rule 9(b) requires that the free services saved the providers money"; and (2) failed to "demonstrate that any independent value to the purchaser was *substantial*." *Id.* at *9-10. *Medtronic* does not provide a defense to the conduct at issue here for two distinct reasons. First, for the reasons discussed above, Defendants' conduct should be analyzed under the CPG guidance that addresses conduct by "prescribing physicians" – not "purchasers." And as OIG has made clear, unlawful remuneration is involved where, as here, (1) a *Prescriber* receives a "service" that would "*eliminate an expense the physician would have otherwise incurred*" or, (2) a service is "*sold to a physician at less than fair market value*." *Id.* (emphasis added). Further, the AC does not suffer from the specificity infirmities that plagued the complaint in *Medtronic*. Here, the Relators have adequately pled that Bayer and Amgen's provision of Free Nurse and Support Services have "independent value," and that the independent value the Prescribers received was "substantial."

This is not a close question. Indeed, Defendants' Free Nurse and Support Services programs very much mirror the type of conduct that has been held – particularly at the pleading stage – to run afoul of the AKS. For instance, in *United States ex rel. Wood v. Allergan, Inc.*, 2017 WL 1233991 (S.D.N.Y. Mar. 21, 2017), the relator alleged that the defendant violated the AKS by providing free patient instruction sheets and prescription pads to prescribers and

patients. The court held that a drug company's service constitutes unlawful remuneration if it eliminates an expense that the Prescriber would have otherwise incurred. *Wood*, 2017 WL 1233991, at *21. In discussing whether these products constituted remuneration under the AKS, the defendant argued "that the supplies lacked any marketing utility as they were provided to patients *after* their surgeries and that the prescription pads could be used only to prescribe Allergan drugs – eliminating any independent value to physicians." *Id.* at *22. The court rejected both arguments. First, the court found that the patient instruction sheets were "'generally regarded' as a 'necessity,' raising the plausible inference that physicians would otherwise have had to cover printing and shipping costs themselves." *Id*. Second, the court found that the prescription pads constituted remuneration under the AKS because, as here, "Allergan provided these goods only to ophthalmologists who agreed to prescribe its drugs (rather than its competitor's drugs), again raising the plausible inference that physicians would otherwise have had to purchase their own prescription pads – or certainly that they would have to purchase general prescription pads more often." *Id*. In rejecting the defendant's argument, the court further found that "the fact that physicians consistently designed and ordered these supplies on Allergan's dime is evidence that they viewed them as having value." *Id.* If anything, Defendants' conduct at issue in this case is far more problematic and raises greater conflicts of interest concerns than that of Allergan. Paying for and providing essential administrative support and nursing services that Prescribers and their staff would otherwise need to undertake has far greater independent value and is more likely to influence a prescription than providing "free patient instruction sheets and prescription pads to prescribers and patients." *See Wood*, 2017 WL 1233991, at *21.

Furthermore, the services Defendants provide to Prescribers and their staff extend well beyond the mere "product support" that Defendants describe in their motion. For example, the Free Nurse program is not tied solely to the use of the prescribed medication. Rather, the program also purports to educate patients on how to manage their treatment and underlying disease. AC ¶¶ 93, 96, 97, 101-103. Similarly, the Support Services program teaches Prescribers and their staff how to effectively navigate the opaque and complicated insurance process. Prescribers can then use these same tools to manage insurance issues for *all* of their patients, including those who do not take Amgen or Bayer drugs.

Similarly, in *United States ex rel. Boise v. Cephalon, Inc.*, 2015 WL 1724572 (E.D. Pa. Apr. 15, 2015), the relator alleged that the defendant, a pharmaceutical manufacturer, violated the AKS by providing certain administrative services to prescribers of its drugs. Specifically, the relator alleged that these free services allowed physicians to obtain "reimbursement from Medicare and Medicaid without having to pay their own staff to perform the work," and that this induced physicians to prescribe defendant's drugs "without concern for the time, resources or lost profits associated with addressing reimbursement issues raised by payors, such as Medicare and Medicaid themselves." *Id.* at *11-12. Applying the CPG standard for prescribing physicians," the court found that these services constituted remuneration because they relieved Prescribers of a responsibility they would otherwise have had to perform and therefore relator adequately alleged a violation of the AKS. *Id.* The conduct at issue in *Boise* largely mirrors the conduct at issue here, and it is illegal for the same reasons.

b. White Coat Marketing by Nurse Educators Violates the FCA

Defendants do not contest – nor could they – that using "nurse educators" as disguised sales people violates the AKS. Instead, Defendants argue that (1) the "nurse educators" were not acting as sales reps; and (2) the AKS has statutory and regulatory "safe harbors" that expressly

permit pharmaceutical companies to engage non-employees to provide services. Neither assertion excuses the conduct at issue in this case.

Defendants' first argument fails because it completely ignores the particularized allegation set forth in the AC. For instance, the AC alleges that:

- The nurse educators received "sales training" from Bayer and Amgen. AC ¶¶ 117-120. The training included (1) "sales techniques"; (2) "how to overcome Prescriber and staff objections"; and (3) "how to market the product[s] to the Prescribers." *Id.* ¶¶ 118-120.
- The nurse educators were actively used by Bayer and Amgen to drive sales. AC ¶¶ 121-24. For instance, Green was given a list of approximately 150 Prescriber offices to target and was expected to collaborate with the sales team. *Id.* ¶ 122. Working in conjunction with Bayer and Amgen sales reps, the nurse educators targeted "high[volume]" Prescribers and "important provider[s]." *Id.* ¶¶ 123-24.
- The White Coat Marketing program helped Bayer and Amgen gain access to Providers who would otherwise not be receptive to sales reps. *Id.* ¶ 129 ("very often now . . . doctor[] offices have posted right on their doors 'we will not see drug reps'. . . [S]o often, I can get my foot in the door"); *Id.* ¶ 130 ("It's getting more difficult now to get in to the oncology offices . . . . So any time you can have access from a nursing point of view that really helps you with . . . promoting your product in that particular practice.").
- The "education" sessions largely focused on the benefits the Bayer and Amgen products would provide. *Id.* ¶¶ 131-39.
- The nurse educators would engage in direct marketing to patients. *Id.* ¶¶ 140-45.

Particularly at the pleading stage, the AC's allegations support Relators' assertion that the nurse educators were nothing more than disguised sales reps for Bayer and Amgen.

Defendants' cursory argument that the challenged conduct may be the subject of a safe harbor similarly fails. It is telling that Defendants have not even attempted to show that the "personal services" safe harbor set forth in 42 C.F.R. § 1001.952(d) applies to the challenged conduct. This is because the safe harbor covers only services that "*do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law*." In other words, conduct that expressly violates the AKS – such as paying direct remuneration to Providers – is not immunized by using an intermediary to recommend products.

Indeed, guidance issued by the DHHS when adopting the safe harbor provisions makes clear that the "personal services" safe harbor does not exempt payments to "health care provider[]" intermediaries who, based on their "position of public trust," thereafter recommend that other health care professionals or patients purchase the products or services of the company from whom they received payment. 56 Fed. Reg. 35952 (1991) ("[W]e have experienced many instances where promoters and consultants have become involved in marketing activities *that encourage health care providers and others to violate the statute . . . . It would be inappropriate to allow such activities to receive safe harbor protection. Thus, we are adding paragraph (d)(6) to this safe harbor provision to make clear that the service that is contracted for is not protected if it involves the counselling or promotion of a business arrangement or other activity which itself constitutes a violation of any State or Federal law*."). The DHHS's interpretation of the safe harbor is entitled to receive significant deference here.[3]

[3] *See generally Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

2. The AC Adequately Pleads Scienter

The AC explicitly alleges that Defendants knowingly and willingly violated the AKS and FCA. AC ¶¶ 8-10, 14, 107, 114-115, 187-188. Further, by pleading extensive details of a scheme that was designed to and succeeded in using kickbacks to induce Prescribers to prescribe Bayer and Amgen drugs, at least some of which have and will be reimbursed by Government programs, Relators have pleaded facts that support a reasonable inference that Defendants acted with the requisite intent.

Defendants do not contest that the AC pleads scienter, both explicitly and by inference. MTD at 15. Instead, Defendants cite cases that stand for the proposition that a party that acted in compliance with a reasonable interpretation of the law cannot be found to have knowingly submitted a false claim. MTD at 15-16. And after positing that the OIG guidance was purportedly "ambiguous," Defendants assert that Relators have failed to plead scienter. MTD at 16-17. Defendants' arguments are meritless.

a. Defendants' "ambiguous guidance" argument is unavailing

Defendants' *post hoc* arguments about the supposedly "ambiguous" nature of the CPG's guidance do not withstand scrutiny.

As an initial matter, as set forth above, the CPG's guidance that applies to Defendants' interactions with "prescribing physicians" is *not* ambiguous. Furthermore, none of OIG's existing guidance immunizes Defendants' conduct because it presents radically different fact patterns. Indeed, it is critical to note that all of the advisory opinions OIG has issued are limited to the "specific arrangement[s] described in [each] letter" and none has "applicability to other arrangements, *even those which appear similar in nature and in scope*." OIG Ad. Op. 00-10, 2000 WL 35747420, at *11 (emphasis added). For that reason, OIG encourages any marketplace actor to seek its own advisory opinion regarding its own conduct. 42 C.F.R. § 1008.11. But

Defendants did not proactively seek OIG's guidance in implementing the challenged marketing schemes. If OIG's guidance were really ambiguous, Defendants certainly should have sought an advisory opinion regarding their conduct. But Defendants instead opted to shoot first, and ask questions later. This alone is sufficient to infer scienter.

Further, "[w]hile it is true that FCA liability does not attach to reasonable but erroneous interpretations of the law . . . the statute requires a defendant *to actually come to* that reasonable but incorrect conclusion." *Waldmann v. Fulp*, 259 F. Supp. 3d 579, 629 (S.D. Tex. 2016) (emphasis added). Defendants' cases – none of which involved a motion to dismiss – are inapposite. The defendants in those cases demonstrated through a *developed record* their actual belief, concurrent with the accused activity, that their actions were legally permissible.[4] Here, Defendants have not asserted that they have at any time actually believed that the accused schemes were lawful under their interpretation of the AKS. Defendants merely set out a supposedly reasonable interpretation that, by all indications, was tailor-made for litigation. Defendants cannot evade FCA liability under these circumstances: "[t]here is no support for the proposition that a defendant may disregard its obligations under the FCA and then argue ex post facto that a reasonable interpretation of applicable law supports its prior position." *Id.* at 629.

In any event, these issues are not suitable for disposition at the pleading stage. The question of whether Defendants reasonably interpreted purportedly "ambiguous" guidance and acted in good faith to comply with the FCA and AKS is heavily fact-intensive and not appropriately adjudicated at the motion to dismiss stage. *See United States ex rel. Banigan v.*

[4] *United States ex rel. Purcell v. MWI Corp*., 807 F.3d 281, 289 (D.C. Cir. 2015) (overturning a jury decision); *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 52 (2007) (affirming dismissal on summary judgment); *United States ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 982 (D.C. Cir. 2008) (affirming dismissal on summary judgment); *United States ex rel. Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d 920, 921 (S.D. Tex. 2007) (granting summary judgment).

Organon USA, Inc., 2013 WL 4786323, at *2 (S.D. Tex. Sept. 6, 2013) ("The majority of courts have held that it is inappropriate to decide a scienter issue, e.g. whether [the defendant] had a 'good faith interpretation of the statute' that would negate the intent necessary for an FCA violation, at the pleading stage of the litigation."); *United States v. Newman*, 2017 WL 3575848, at *8 (D.D.C. Aug. 17, 2017) ("Defendant's allegedly reasonable interpretation of FCC regulations may eventually prevent the government from proving knowing falsity in this case, but the argument requires the development of a factual record. The Court will not dismiss this case at the outset merely because the allegations in the complaint are rebutted by assertions about Defendant's state of mind in her briefing on her motion to dismiss."); *United States ex rel. Wood v. Allergan, Inc*., 246 F. Supp. 3d 772, 829 (S.D.N.Y. 2017) (finding that defendants' "reasonable interpretation" defense did not warrant dismissal, noting that "[a]t a minimum, they raise questions of fact that cannot be resolved at this stage of the proceedings"); *United States ex rel. Nevyas v. Allergan, Inc*., 2015 U.S. Dist. LEXIS 86243, at *18 (E.D. Pa. July 2, 2015) (defendant's "reasonable interpretation of the law and applicable regulatory framework may well be a defense to liability, but it is not appropriate at the motion to dismiss stage when there are reasonable interpretations to the contrary"); *United States ex rel. Pasqua v. Kan-Di-Ki LLC*, 2012 WL 12895229, at *7 (C.D. Cal. June 18, 2012) (noting that "while ambiguity is relevant to the scienter inquiry, it does not preclude a finding of liability under the FCA unless no issues of fact remain" regarding the defendant's state of mind); *United States v. Estate of Rogers*, 2001 WL 818160, at *4 (E.D. Tenn. June 28, 2001) (noting that "defendants' contention that they made a reasonable interpretation of HCAC's related-party rules and regulations only goes to the scienter element and whether the defendants acted 'knowingly' . . . is a matter for the jury to determine at trial").

b. Relators have adequately plead scienter

Although fraud claims are subject to a heightened pleading standard, "allegations regarding scienter may be pleaded generally" and still comply with Rule 12(b)(6) and Rule 9(b). *United States ex rel. McLain v. Fluor Enters*., 2013 WL 3899889, at *8 (E.D. La. July 29, 2013). The AC contains both direct allegations of such intent – which must be accepted as true – as well as numerous allegations from which a reasonable inference of intent to defraud the government can be inferred.

The AC plausibly alleges that each Defendant knowingly and willingly violated the FCA and AKS. Relators explicitly state that Defendants are aware of the prohibitions of the AKS, but disregarded those prohibitions in order to maximize profit. *See, e.g.*, AC ¶¶ 14, 85, 115, 131.

In addition to these explicit allegations of intent, Relators "may satisfy the FCA's scienter requirement with general allegations, as long as he sets forth specific facts supporting an inference of fraud." *United States ex rel. Woodard v. DaVita, Inc*., 2011 WL 13196556, at *8 (E.D. Tex. May 9, 2011). "The inference may be drawn by alleging facts showing a defendant's motive or by identifying circumstances that indicate conscious behavior on the part of the defendant." *United States v. Americus Mortg. Corp*., 2014 WL 4274279, at *9 (S.D. Tex. Aug. 29, 2014) (citing *Tuchman v. DSC Communications Corp*., 14 F.3d 1061, 1068 (5th Cir. 2003)). At the pleading stage, to support their claims of AKS violations, Relators need only present evidence that Defendants "knowingly and willfully solicited, offered, paid, or received 'remuneration (including any kickback, bribe, or rebate) *directly or indirectly, overtly or covertly, in cash or in kind*' that is intended to induce a referral for an item or service for which payment can be made from a Federal healthcare program." *Waldmann*, 259 F. Supp. 3d at 616 (citing 42 U.S.C. § 1320a-7b(b)) (emphasis added); *see also United States ex rel. Wall v. Vista Hospice Care, Inc*., 2016 WL 3449833, at *21 (N.D. Tex. June 20, 2016). "It is not necessary to

show that inducing referrals was the primary purpose of the remuneration." *Waldmann*, 259 F. Supp. 3d at 617.

The AC's allegations strongly support an inference that Defendants acted with the intent to violate the AKS. They also support an inference that the Defendants knew, or at the very least were deliberately indifferent or in reckless disregard of the fact that these kickbacks would result in the submission of false claims. That is all that is required to satisfy the FCA's scienter element. *See, e.g., United States ex rel. Parikh v. Brown*, 587 Fed. App'x 123, 129 (5th Cir. 2014). Relators have alleged that Defendants are aware of the prohibitions of the AKS. AC ¶¶ 8, 9, 11-14. They have described Defendants' motives – driving profits through increased prescriptions. AC ¶14 ("Although Bayer and Amgen, as well as their co-defendants, knew that the AKS prohibited them from providing anything of value to providers or from giving kickbacks to promote the Covered Products, Defendants disregarded the law" in order to maximize sales); *Id.* ¶ 94 ("Seeking to exploit the needs of Prescribers and healthcare organizations and the challenges they face in managing patients affected by chronic diseases, Bayer and Amgen developed a marketing strategy that involved furnishing nurse educators to Prescribers to induce them to prescribe the Covered Products."); *Id.* ¶ 99 ("In most cases they'll go, 'Well, we [Prescribers] don't have the time to be able to [do patient training] for our patients.' And a lot of times they'll talk to the sales people that *they're prescribing specifically to get a beta nurse*."); *see also Id.* ¶¶ 88, 108, 146.

The AC also explains the nature of the financial benefit the nurse educator and reimbursement support services confer on providers. *See e.g.*, AC ¶ 98 ("Prescribers were encouraged to enroll all patients using the Covered Products into these patient support programs so that the nurse educators could begin to directly manage these patients and free the Prescriber

from the time and expense of doing so."); *Id.* ¶¶ 100-06 (describing the tangible benefit the nurse educator program conferred on Prescribers); *Id.* ¶ 107 ("The nurse educators are effectively free employees given to Prescribers in exchange for the Prescribers' commitment to recommend the Covered Products over competing products."); *Id.* ¶¶ 151-167 (describing the tangible benefits reimbursement support services conferred on Prescribers). Taken together, Relators have pleaded numerous facts that, when accepted as true, unquestionably support an inference that Defendants knowingly and willfully offered and paid remuneration with the intent of inducing Prescribers to prescribe Defendants' drugs. This adequately pleads scienter. *See Americus Mortg. Corp.*, 2014 WL 4274279, at *9-10 (finding scienter adequately plead where the government provided details of the fraudulent scheme and alleged that defendant submitted documents "'knowingly or . . . with deliberate ignorance and/or with reckless disregard for the truth,'" with the motive of profiting at the expense of the government).

The AC also contains allegations demonstrating that the White Coat Marketing program was orchestrated by Defendants to unlawfully promote Bayer and Amgen products, and that the nurse educators were compensated for their promotional activities. *See, e.g.*, AC ¶ 115 ("Although the nurses were independent contractors and were purportedly 'educators,' they were expected to and did recommend the Covered Products."); *Id.* ¶ 117 ("Bayer and Amgen invested heavily in training nurse educators how to gain access to Prescribers and promote the covered products. This training was a *vital* component of Bayer and Amgen's scheme because Bayer and Amgen's ultimate goal was to drive sales."); *Id.* ¶¶ 118-120 (describing how nurse educators were hired and trained to promote Defendants' drugs as part of their job responsibilities); *Id.* ¶¶ 121-145 (setting forth the evidence demonstrating that the nurse educators were expected to and did in fact promote Defendants' products in contravention of the prohibition on white coat

marketing); *Id.* ¶ 150 ("Bayer and Amgen's drug reps and Lash's reimbursement support services representatives marketed the Support Services when detailing Bataseron and Nexavar to increase the likelihood that prescribers would prescribe these drugs."). The AC also alleges that Defendants knew that such activities violated the AKS, explaining that the goal of Defendants' conspiracy was to try to "disguise this marketing strategy" and "circumvent the law." *Id.* ¶¶ 113-155; *Id.* ¶ 145 ("By providing remuneration to Lash, Amerisource, and Ashfield to employ and deploy 'white coated' nurses to recommend the Covered Products, the Defendants violated the AKS."). In short, the AC describes in detail a complex yet focused effort to hide Bayer and Amgen's role in the nurse educator marketing scheme behind a multi-party administrative chain. These allegations support a reasonable inference that Defendants developed and carried out the nurse educator marketing scheme with the intent of promoting Bayer and Amgen products in violation of the AKS. Nothing more is required under Rule 12(b)(6) or Rule 9(b).[5]

The AC contains numerous plausible allegations describing in detail the planning, execution, and goals of the fraudulent schemes at the heart of Relators' FCA claims. These schemes involved five different businesses, numerous nurses and support services staff, and were

[5] Although Defendants claim that facts alleged in the AC "contradict any 'knowing' violation under Theory Two," this argument relies on misrepresentations of Relators' allegations. MTD at 17. While Defendants describe the nurse educators as explaining that their role was to educate and not recommend Defendants' products, the actual language used by the nurses as set out in the AC shows their understanding that their ultimate goal was to promote Bayer and Amgen products. *See* AC ¶ 136 (quoting a nurse educator explaining that the nurses "were there to help educate. To get them [Prescribers] to understand . . . and consequently then, that product, was now going to be helpful for the patient."); *Id.* ¶ 132 ("It's not that you can't say the other company's names, drugs, therapies, whatever, but you can't discuss it at all;" "we're only allowed to talk about our particular drug. We don't really get into other therapies."); *Id.* ¶ 125 ("It was such a big plus for the sales rep to be able to travel with a Beta nurse."); *Id.* ¶ 130 ("It's getting more difficult now to get in to the oncology offices primarily because of the Sunshine Act . . . [s]o any time you can have access from a nursing point of view that really helps you with . . . promoting your product in that particular practice."). Regardless, this only raises a question of fact, which does not warrant dismissal of a complaint.

executed on a national scale at Bayer and Amgen's expense. Taken in the light most favoring Relators, the AC supports at least two reasonable inferences. First, the AC shows that this massive undertaking was performed with the intent of inducing Prescribers to prescribe Bayer and Amgen products in exchange for the benefits provided by Defendants. Second, the AC's description of the complex, multi-party system to administer the nurse education and reimbursement support services demonstrates that Defendants were intentionally seeking to hide the trail of their activities. Together, this supports the inference that Defendants' violations of the AKS were knowing and willing, and that Defendants acted with at least reckless disregard to the submission of tainted false claims. This is sufficient to plead intent. *See Americus Mortg. Corp*., 2014 WL 4274279, at *9-10 (finding scienter adequately pleaded where the government provided details of the fraudulent scheme and alleged that defendant submitted documents "'knowingly or . . . with deliberate ignorance and/or with reckless disregard for the truth,'" with the motive of profiting at the expense of the government); *Parikh,* 977 F. Supp. 2d at 670-71 (finding that an inference that a kickback scheme existed "[wa]s particularly strong given that it would make little apparent economic sense" for the defendant to provide services at a financial loss "unless it were doing so for some ulterior motive—a motive Relators identify as a desire to induce referrals").

B. The AC's Allegations Satisfy Rule 9(b)

The AC describes the three intertwined schemes designed and executed by Defendants to (a) deploy kickbacks to induce Prescribers to prescribe Bayer and Amgen products and, in doing so, (b) maximize the profits and business opportunities for each Defendant. In dozens of detailed paragraphs, Relators' allegations set out the particulars of Defendants' schemes, including the role each Defendant played. These allegations are based on the personal knowledge of Relator Green and *seven* other confidential informants, each of whom had a role in promoting and/or

administering Defendants' Free Nurse, White Coat Marketing, and Support Services programs. AC ¶ 87. Yet Defendants contend that Relators have failed to satisfy Rule 9(b), asserting that the AC does not provide "any specifics" regarding the accused schemes. MTD at 21. Defendants' arguments are built on a misrepresentation of the AC and a misapplication and misuse of Rule 9(b).

1. FCA Claims Are Reviewed According to a Flexible and Relaxed Standard

The primary purpose of Rule 9(b) is to provide adequate notice of the nature and grounds of the fraud claim such that the defendant can prepare an effective defense. *See Hart v. Bayer Corp*., 199 F.3d 239, 247 n.6 (5th Cir. 2000); *Frith v. Guardian Life Ins. Co. of Am*., 9 F. Supp. 2d 734, 742 (S.D. Tex. 1998). The AC provides more than enough detail for each Defendant to understand the basis of Relators' claims against them.

Indeed, the level of detail regarding the "who, what, when, where, how" that Defendants point to as purportedly missing from the AC is not necessary for Defendants to comprehend Relators' claims. Nor are these details necessary to adequately plead FCA claims. The Fifth Circuit expressly rejects a standard for Rule 9(b) that stringently requires that the "who, what, when, where, and how" of each allegedly false claim presented to the government be pleaded in a relator's complaint. *See, e.g.*, *Grubbs*, 565 F.3d at 190 (finding that Rule 9(b) does *not* require that FCA complaints allege details regarding the fraud such as names, dates, billing numbers, and amounts). Instead, the Fifth Circuit established a relaxed standard by which Rule 9(b) is applied with flexibility in consideration of the specific circumstances of a case. *Id.; see also United States ex rel. Parikh v. Citizens Med. Ctr*., 977 F. Supp. 2d 654 (S.D. Tex. 2013), *aff'd sub nom., United States ex rel. Parikh v. Brown*, 587 Fed. App'x. 123 (5th Cir. 2014); *United States ex rel. Ruscher v. Omnicare, Inc*., 2014 WL 2618158, at *10 (S.D. Tex. June 12, 2014).

Contrary to Defendants' assertions, "the time, place, contents, and identity standard is not a straitjacket for Rule 9(b)." *United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 715 (N.D. Tex. 2011) (citing *Grubbs*, 565 F.3d at 188-190) (noting that "the standard for stating a claim for relief with particularity is lower in the FCA context than it is in the securities or common law fraud contexts"). Furthermore, "[s]chemes that span several years and involve multiple acts are subject to a relaxed 9(b) pleading standard."[6] *United States ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 822 (E.D. Tex. 2008) (collecting district court cases from Fifth Circuit); *United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 768-69 (S.D. Tex. 2010). In such cases, fraud may be pleaded upon information and belief so long as the relator pleads the fraudulent scheme with particularity and provides representative examples of specific fraudulent acts conducted pursuant to that scheme. *See Foster*, 587 F. Supp. 2d at 821-22; *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 509-510 (5th Cir. 2007).

The AC meets these standards in spades.

2. The AC Adequately Describes the Fraudulent Activity Underlying Relators' Claims

The AC contains detailed allegations of Defendants' schemes from both a high-level and up-close perspective, based in large part on actions that were witnessed and/or performed by the confidential informants and Green. Defendants nonetheless assert that Relators have failed to describe the "who, what, when, where, and how" that they claim is required by Rule 9(b). MTD at 21. Defendants also describe Relators' significant work in compiling the information for the

[6] The pleading requirements of Rule 9(b) are also relaxed where, as here, facts relating to the alleged fraud are peculiarly within the defendant's knowledge. In these circumstances, fraud may be pleaded upon information and belief. *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997).

AC as a "superficial investigation." *Id.* Rhetoric is no substitute for analysis: the level of detail contained in the AC both satisfies Relators' burden under Rule 9(b) and reflects the seriousness of Relators' efforts to bring this litigation.

The AC provides sufficient detail to satisfy Rule 9(b) in accordance with the Fifth Circuit's standards. As demonstrated above, the AC contains plausible, detailed allegations describing: Defendants' motives (AC ¶¶ 14, 94, 99); the development and administration of the nurse education program by Bayer, Amgen, and Amerisource ((Scheme 1) AC ¶¶ 92-95); the scope of the Free Nurse program and the benefits the program confers on Prescribers and their staff, which induce them to prescribe the Covered Products (AC ¶¶ 97-107); the manner in which nurses that participate in the White Coat Marketing program are trained, expected to and ultimately do in fact promote the Bayer and Amgen products ((Scheme 2) AC ¶¶ 108-144); the development of the Support Services program by Bayer, Amgen, and Amerisource ((Scheme 3) AC ¶¶ 146-150); an explanation of how the Support Services program functions and how it provides benefits to Prescribers and their staff that induce them to prescribe Bayer and Amgen products (AC ¶¶ 151-167); the nation-wide scope of the schemes (AC ¶¶ 184-190); the time-frame of the expansive and long-lasting schemes (AC ¶¶ 184-188); the Government Programs that reimburse prescriptions for the Covered Products (AC ¶¶ 43-86); an explanation of why claims submitted to the Government programs for the Covered Products are false claims (AC ¶¶ 3-15, 29-38, 47-57, 67, 68, 80, 85, 188, 190-204); and an explanation of why Defendants knew that these false claims would be submitted (AC ¶¶ 85, 161, 184-204). This level of detail satisfies Relators' Rule 9(b) obligations. *See United States ex rel. Ramsey-Ledesma v. Censeo Health, L.L.C.*, 2016 WL 5661644, at *6 (N.D. Tex. Sept. 30, 2016) ("The Fifth Circuit has held that a complaint for violations of the FCA satisfies Rule 9(b) as to individual defendants where,

as here, the complaint sets out "the particular workings of a scheme that was communicated directly to the relator by those perpetrating the fraud.") (citing *Grubbs*, 565 F.3d at 191); *Ruscher*, 2014 WL 2618158, at *10 (for FCA claims, Relators need only provide a relevant time frame and "sketch how it was that Defendant[s] provided remuneration to its clients, the form of that remuneration, how and why Defendant[s] believed that remuneration would induce new business, and how Defendant[s] benefited from the remuneration").

Defendants argue that the AC lacks specificity as to the timeframe for Relators' claims, the identification of individual doctors, patients, or other participants in the scheme such as the individuals who trained the nurses in the Free Nurse program. MTD at 22-24. Defendants also complain that the AC does not identify any doctors or patients that were influenced by Defendants' White Coat Marketing program. MTD at 24.

These arguments rely on a selective reading of the AC. On pages 58 and 59 of the AC, for instance, Relators provide *fifteen examples* of doctors who were targeted with the Free Nurse program. In any event, the type of detail Defendants allege is missing is not required to satisfy Rule 9(b). "Relators do not have to identify the specific individuals who participated in the fraud," nor do they have to provide specific dates or locations of instances of the fraud within the alleged scheme. *Wall*, 778 F. Supp. 2d at 720 (finding claims adequately plead where relator provided details of a scheme "allegedly drawn from her personal observations"); *see also Grubbs*, 565 F.3d at 190 ("To require these details at pleading is one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates."). Furthermore, "Relators do not need to identify any actual referrals or successful inducements to prove a violation of the AKS; they only have to show that Defendants knowingly paid remuneration in

exchange for referrals, not that they were successful." *Parikh*, 977 F. Supp. 2d at 665 ("*Grubbs* establishes that Relators need not identify particular claims resulting from the kickback scheme," nor allege exact dollar amounts or billing dates); *Ruscher*, 2014 WL 2618158, at *12 ("With respect to inducement, all that Relator must do is plead that Omnicare acted with the intent to induce referral of federal health care program business."); *Allen v. Beta Const.*, 309 F. Supp. 2d 42, 47 (D.D.C. 2004) (noting that "while significant details . . . are indeed absent, these details are not necessary at this very preliminary stage of litigation. Indeed, plaintiff, having first stated a claim with sufficient specificity, must be allowed to fill in those details through the discovery process, especially because these details are in 'defendants' possession and will be identified when produced in discovery.")

Finally, Defendants assert that "Relators offer no detail whatsoever" to support the "bald and conclusory allegations" that the Free Nurse and Support Services programs confer a tangible benefit on Prescribers and their staff. MTD at 23, 25. This is wishful thinking. *See supra* at 3-4. And while Defendants argue that Relators do not identify doctors that "eliminated staff positions . . . or otherwise received 'substantial value' as a result of the services" (MTD at 23), this is a red herring. This type of information is not necessary (a) to demonstrate that the Defendants' schemes provided benefits to Prescribers, (b) to support an AKS or FCA violation, or (c) to understand the nature of Relators' claims. The AC provides sufficient information to provide Defendants with fair notice of Relators' claims and establish their factual foundation. Relators have therefore met their obligations under Rule 9(b).

3. The AC Has Adequately Plead that False Claims Were Submitted as a Result of the Fraudulent Schemes[7]

The AC describes how Defendants' schemes were planned to induce Prescribers to prescribe Bayer and Amgen products in violation of the AKS, and that false claims were submitted as a result of these tainted prescriptions. Defendants argue that Relators fail to satisfy Rule 9(b) because they "provided no detail regarding the submission of false claims." MTD at 26, 27. To support this argument, Defendants cherry-pick the AC's allegations and ignore just about everything else Relators allege. MTD at 28, 29. Defendants' arguments fail. Taken as a whole and reviewed in the light most favorable to Relators, the AC's allegations adequately plead that false claims were submitted as a result of Defendants' fraudulent schemes.

Although Relators must demonstrate a causal link between Defendants' fraudulent activities and the submission of false claims, Relators do not have to identify any specifically induced prescriptions or false claims. Relators may also satisfy their pleading requirements by alleging "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Ramsey-Ledesma*, 2016 WL 5661644, at *6 (citing *Grubbs*, 565 F.3d at 190) ("The SAC is not fatally deficient because it does not provide a specific date or location when and where any allegedly false diagnosis was made or any allegedly false code was entered, nor because it does not name a physician who made an allegedly false diagnosis or a coder who entered an allegedly false code.").

The AC contains allegations that constitute reliable indicia that support the inference that these schemes resulted in the filing of false claims. For instance, the AC indicates that between 70% and 95% of Prescribers utilized Support Services. AC ¶ 164. The AC also alleges that the

[7] Defendants present causation arguments under both Rule 12(b)(6) and Rule 9(b). In the interest of avoiding redundancy, Relators address causation under the more demanding Rule 9(b) standard.

White Coat Marketing program targeted high-volume Prescribers. *Id.* ¶¶ 123-24. Finally, the AC identifies the number of Medicare claims submitted for several Bayer and Amgen products, as well as Medicaid claims from numerous states. *Id.* ¶¶ 191-204. Accepted as true, these allegations plausibly support an inference that false claims were submitted.

At bottom, the AC sets forth ample details, unlike the dismissed complaints in Defendants' cited cases.[8] Relators have also done far more than allege "publicly available information regarding Medicare and Medicaid reimbursement." MTD at 29. Relators have submitted plausible allegations that establish a nexus between the fraudulent schemes and the submission of claims to Government programs for the Covered Products. For example, the AC reveals testimony of confidential informants explaining that the schemes had the effect of increasing prescriptions of Defendants' drugs. AC ¶¶ 16-17 (alleging that prescribers increased the number of prescriptions written for Defendants' drugs because of the benefits conferred through the Free Nurse and Support Services programs and as a result of Defendants' White Coat Marketing program); *Id.* ¶¶ 99, 105 (nurse educator program induced Prescribers to

[8] *See Foster*, 587 F. Supp. 2d at 824 (noting that relators did not name any physician who issued tainted prescriptions, nor connect the prescriptions to Medicaid, nor describe an instance in which a physician selected the relevant drug over a competitor, nor provide general statistical information to indicate the frequency with which OHP doctors prescribed BMS drugs); *United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 784 (S.D. Tex. 2010) ("[R]elators have not alleged that Medtronic caused any physicians or hospital to make false certifications of compliance."); *United States ex rel. Lam v. Tenet Healthcare Corp.*, 481 F. Supp. 2d 689, 698 (W.D. Tex. 2007) (noting that relators did not identify anyone who offered remuneration, did not give information regarding relevant financial arrangements suggesting that the arrangements were illegal or made for the purposes of inducement); *United States ex rel. Kroening v. Forest Pharm., Inc.*, 155 F. Supp. 3d 882, 894 (E.D. Wis. 2016) (noting that relator did not provide details regarding false claims that would have been in his possession as a sales representative for defendant); *United States ex. rel. Kelly v. Novartis Pharm. Corp.*, 827 F.3d 5, 15 (1st Cir. 2016) ("Relators failed, however, to tie these independently unexceptional allegations together into particularized charges about specific fraudulent claims for payment."); *United States ex rel. King v. Alcon Labs.*, Inc., 232 F.R.D. 568, 572 (N.D. Tex. 2005) (noting that relator failed to identify anyone involved in the fraud and "failed to allege any facts as to exactly how the fraud was committed").

prescribe the Covered Drugs); *Id.* ¶¶ 118, 142 (white-coat marketing persuaded Prescribers to prescribe the covered drugs); *Id.* ¶ 165 (reimbursement support program induced Prescribers to prescribe the covered drugs); *Id.* ¶ 176 (because of Defendants' kickbacks, "Prescribers and nurses may consciously or subconsciously recommend the Covered Products despite cheaper alternatives or more effective treatments"). The AC also explicitly states that through the reimbursement support services, Defendants assisted Prescribers and their staff with obtaining pre-authorization and reimbursement from Medicaid and Medicare. AC ¶¶ 160, 161. Further, while Defendants claim that there are no allegations that the programs were conditioned on the Prescribers prescribing the Covered Drugs (MTD 29 n. 10), the AC specifically states that, for example, the reimbursement support services "give Prescribers a means to 'outsource' [managing reimbursements], but *only if* the Prescriber prescribes Betaseron or Nexavar." AC ¶ 167.

These allegations, taken as true, establish that Defendants' Free Nurse, White Coat Marketing, and Support Services programs had the effect of inducing physicians to prescribe Bayer and Amgen products, and that at least some of those prescriptions were submitted to Medicaid and Medicare for reimbursement. This is sufficient to give rise to the "strong inference" that false claims were in fact submitted. *See United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1037 (C.D. Cal. 2016) (evidence showing that defendant "engaged in a systematic campaign to promote off-label prescriptions of its drugs, that physicians who received more promotional contacts prescribed at a higher rate than those who received fewer contacts, and that claims for off-label prescriptions were presented to the government in the hundreds of thousands following Celgene's promotional activities—constitutes 'sufficiently detailed circumstantial evidence' that false claims were presented as a result of Celgene's

conduct"); *United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 492 (S.D. Tex. 2011) (denying motion to dismiss despite fact that the complaint "fail[ed] to assert that the alleged off-label promotion caused a specific physician or physicians to write these prescriptions").

While Defendants argue that the AC does not specifically identify patients or doctors who actually submitted false bills, or of doctors who were induced to prescribe the Covered Products by Defendants' kickbacks, this information is not necessary to satisfy the Fifth Circuit's Rule 9(b) standard. *See, e.g., Parikh*, 977 F. Supp. 2d at 665 (noting that relators do not need to identify any actual referrals or successful inducements to prove a violation of the AKS); *United States ex rel. Tucker v. Christus Health*, 2012 WL 5351212, at *4 (S.D. Tex. Oct. 23, 2012) ("Relator does not identify each false bill by date and patient name, nor does she identify each individual who participated in submitting the false bills to Medicare. Her allegations, however, are adequately particular to survive Defendants' Motion to Dismiss pursuant to Rule 9(b).") Nor does the AC need to specifically identify a false claim that was submitted because of Defendants' fraudulent scheme. *See Ramsey-Ledesma*, 2016 WL 5661644, at *6; *United States ex rel. DeKort v. Integrated Coast Guard Sy*s., 705 F. Supp. 2d 519, 531, 545 (N.D. Tex. 2010) (finding that relator's FCA claim survived where relator "alleged the details of the alleged false claims, as well as the details of a scheme to submit false claims, along with sufficient indicia to lead to a strong inference that the claims were actually submitted").

Indeed, courts have found that causation was adequately pleaded in complaints with similar allegations as those in the AC. *See, e.g., United States ex rel. Cestra v. Cephalon, Inc.*, 2015 WL 3498761, at *5 (E.D. Pa. June 3, 2015) (finding causation adequately pleaded for FCA claims, despite lack of evidence of an actual submitted false claim, where the complaint alleged (1) increase in defendant's drug sales as a result of the fraudulent program and (2) defendant's

use of a reimbursement support program to ensure that the prescriptions were actually reimbursed by the government); *United States v. Toyobo Co.*, 811 F. Supp. 2d 37, 48 (D.D.C. 2011) (noting that allegations "that Toyobo marketed Zylon to the vest manufacturers, and that Toyobo induced with the prospect of refunds, rebates, and reimbursements vest manufacturers and other companies in the Zylon supply chain to continue producing Zylon products . . . amply satisfy the causation requirement"). The AC accordingly contains sufficient allegations to support a strong inference that false claims were submitted as a result of Defendants' fraudulent schemes.[9] Relators' claims should not be dismissed because of a failure to plead causation.

4. The AC Adequately Describes Each Defendants' Role in the Schemes

Defendants accuse Relators of "lumping" the Defendants together, noting that not all Defendants were involved in every aspect of the fraudulent schemes. MTD at 31, 32. The AC explicitly describes the role each Defendant played in the larger, jointly-executed scheme to violate the FCA. AC ¶¶ 92, 107, 113-115, 140, 145, 146, 148-150, 160, 163-64, 168. "The allegation that Defendants are inter-related and that they acted together does not alone require dismissal under Rule 9(b)." *United States ex rel. Tucker v. Christus Health*, 2012 WL 5351212, at *4 (S.D. Tex. Oct. 23, 2012); *Ramsey-Ledesma*, 2016 WL 5661644, at *9 (noting that a complaint adequately pleads as to each defendant if it "distinguishes between the two entities and describes the parties' relationship with each other and to the scheme"). At the pleading stage, Relators are "required only to plausibly allege that each Defendant 'knowingly carried out'

[9] Defendants argue that Prescribers may have prescribed the Covered Products because of the merits of those drugs. MTD at 29 n. 9. At best, Defendants establish a question of fact as to whether their conduct actually caused false claims to be filed. This question of fact is "inappropriate for resolution on a motion to dismiss." *Rotstain v. Trustmark Nat'l Bank*, 2015 WL 13034513, at *11 (N.D. Tex. Apr. 21, 2015) (declining to dismiss plaintiff's complaint on causation grounds).

their part in the alleged scheme." *State Farm Mut. Auto. Ins. Co. v. Pointe Physical Therapy, LLC*, 107 F. Supp. 3d 772, 786 (E.D. Mich. 2015); *Mikes v. Strauss*, 889 F. Supp. 746, 751 (S.D.N.Y. 1995) (noting that the "Court never expected plaintiff to be able to detail every aspect of defendants' alleged fraudulent scheme prior to conducting any discovery"). Moreover, the fact that some Defendants did not participate in all aspects of the scheme does not warrant dismissal. *United States v. Mandel*, 415 F. Supp. 1033, 1047 (D. Md. 1976) ("It is true that defendants Cory and Kovens are named in only the first part of the scheme . . . and not the second part . . . . However, it is not necessary that each defendant be named in every part of the scheme as long as he plays a role in some part of that scheme."); *State Farm*, 107 F. Supp. 3d at 786 ("Each of the Defendants is on fair notice of what it is they are alleged to have done for their part in carrying out the alleged fraudulent scheme to obtain payment for medically unnecessary services and tests. Their claims that they were just carrying on their normal business routines, independent of one another, of course are of no moment at this pleading stage."). Because the AC explains each Defendant's role in the Defendants' fraudulent schemes – which were described in extensive detail as conveyed by multiple parties with personal knowledge – each Defendant is able to understand the nature of the Relators claims against them. Relators have accordingly satisfied both the goal and the standard for Rule 9(b).

C. The AC Adequately Pleads Relators' Conspiracy Claims

Having established their underlying FCA claims, Relators also allege sufficient facts to support their claim that the Defendants conspired to violate the AKS and FCA.[10] Defendants

[10] Defendants misplace reliance on *United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487 (S.D. Tex. 2003), to argue that Relators' conspiracy claims should be dismissed. Unlike the plaintiff in *Graves*, Relators have adequately pleaded the FCA violations at the heart of Defendants' unlawful agreement. *See id.* at 509. Relators' conspiracy claim is equally well-pleaded.

argue that Relators' conspiracy claim fails because Relators do not allege with sufficient particularity that the Defendants had an unlawful agreement to conspire with each other.[11] MTD at 33. But the precedent in this Circuit does not support Defendants' conclusion.

To survive a motion to dismiss, the AC need only demonstrate sufficient evidence to allow a reasonable inference that Defendant implicitly agreed to a scheme that would result in the filing of false claims. *Waldmann*, 259 F. Supp. 3d at 631. In the Fifth Circuit, Relators do not need to show direct evidence of a conspiracy to survive a motion to dismiss. Rather, "each element may be inferred from circumstantial evidence . . . . The illegal agreement may even be silent and informal." *United States v. Gibson*, 875 F.3d 179, 186 (5th Cir. 2017) (internal citation omitted). Further, "[r]elators are not required to demonstrate the manner in which the agreement came into being, only that an agreement did, in fact, exist." *Waldmann*, 259 F. Supp. 3d at 631.

The AC satisfies this pleading standard. It alleges that: (1) all defendants were aware of the AKS and disregarded the fact that the alleged schemes violated the AKS (¶ 16); (2) each of the defendants had a critical role, described in detail, in the alleged schemes (¶¶ 46, 88-91, 94-99, 107-115, 140-150, 160); and (3) the express purpose of the cooperation among Defendants

[11] In a footnote, Defendants also argue claims of a conspiracy between Amerisource and Lash are barred because "a corporation cannot conspire with its own subsidiary." MTD 33-34 fn. 34. The question as to whether this rule applies to conspiracies outside of the antitrust context is not settled in the Fifth Circuit, but courts generally lean towards limiting its application to conspiracies under Section 1 of the Sherman Act. *See ASARCO LLC v. Americas Min. Corp.*, 382 B.R. 49, 79 (S.D. Tex. 2007) (declining to dismiss claims for conspiracy between a parent and subsidiary corporation outside of the Section 1 context); *Ashlar Fin. Servs. Corp. v. Sterling Fin. Co.*, 2002 WL 206439, at *6 (N.D. Tex. Feb. 8, 2002) (same). In any event, the case-law cited by defendants is distinguishable in that all of the defendants were part of the same corporate entity and the conspiracy was limited *only* to parents and subsidiaries. *See United States ex rel. Reagan v. E. Texas Med. Ctr. Reg'l Healthcare Sys.*, 274 F. Supp. 2d 824, 856 (S.D. Tex. 2003). The AC, in contrast, describes the agreement between Amerisource and Lash with several other unrelated entities. The law cited by Defendants therefore does not bar Relators' claims.

was to hide violations of the AKS. *See e.g.*, AC ¶¶ 4-6 (describing cooperation among defendants to provide remuneration and deploying nurses as "undercover sales reps" with the goal of inducing prescriptions); *id.* ¶¶ 14; 108-116 (describing Amerisource, Lash, and Ashfield's role in hiding Bayer and Amgen's illegal remuneration and promotion schemes). These specific and detailed allegations, when taken as true, allow a reasonable inference that Defendants agreed, either explicitly or implicitly, to work together to enact a kickback scheme that would result in the filing of millions of dollars of false claims, thereby defrauding the government in exchange for their own profit. While additional evidence of this conspiracy will come to light during fact discovery, nothing more is needed at the pleading stage.[12] *See In re S. Scrap Material Co., LLC*, 541 F.3d 584, 587 (5th Cir. 2008) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007) (noting that the Supreme Court's plausibility standard for complaints only requires "enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary claims or elements"). Defendants' motion to dismiss Relators' conspiracy claim should be denied.

D. The AC Adequately Pleads Relators' State Law Claims

As Relators have established their Federal claims for violations of the FCA, they have likewise adequately pleaded their claims under the FCA's state-law analogs. Defendants' conclusory assertions to the contrary are unavailing. MTD at 34.

[12] The cases cited by Defendants in support of dismissal of Relators' conspiracy claim concerned complaints with far less detail, and are therefore inapposite. *See* MTD at 33; *United States ex rel. Johnson v. Shell Oil Co.*, 183 F.R.D. 204, 206 (E.D. Tex. 1998) (dismissing conspiracy claims in a complaint that "[did] not provide any factual allegations even hinting at the existence of conspiracy"); *McLain*, 2013 WL 3899889, at *10 (dismissing complaint in which "plaintiffs have not provided [] any indication that any of the parties actually agreed to enter into the alleged conspiracy").

Defendants argue that because state false claims laws are analogous to the FCA and are generally interpreted under the same standards, Relators' claims under state false claims laws fail together with Relators' claims under Federal law. MTD at 34. But as demonstrated, the AC adequately pleads Relators' federal claims. *See supra.* Moreover, there are in fact meaningful distinctions between the elements required under the AKS and FCA, on the one hand, and their state equivalents, on the other. As an example, the Texas Medicaid Fraud Prevention Act ("TMFPA") differs substantially from the FCA. For instance, the TMFPA does not include or require the presentation of a "false claim." Instead, the TMFPA proscribes 13 enumerated unlawful acts, which generally describe material false statements and misrepresentation affecting the Medicaid program. *Compare* 31 U.S.C. §§ 3729(a)(1)(A)-(G) *with* Tex. Hum. Res. Code §§ 36.002(1)-(13). Defendants' complete failure to analyze each of the applicable state equivalents to the AKS and FCA, let alone account for the differences in the statutory schemes, is sufficient reason to deny the motion to dismiss.

Defendants' secondary argument that Relators' state FCA claims should be dismissed because the AC does not contain state-specific allegations similarly fails. The AC contains evidence from confidential informants who have knowledge of the perpetration of the accused schemes *throughout the United States*. AC ¶ 87. The AC also alleges that Defendants deployed their fraudulent schemes "across the nation, and the Covered Products were marketed prescribed, and sold nationwide. Claims were submitted to federal and state healthcare programs, including Medicare and Medicaid, in most, if not all, states for each of the covered products." AC ¶ 59. Details regarding Defendants' pharmaceutical sales, which were tainted by kickbacks, are provided for all 50 states. AC ¶¶ 192-204. Furthermore, courts in this Circuit follow the rule that supplemental jurisdiction of state-law claims should only be declined in the case of

exceptional circumstances. *See Cty. of El Paso, Tex. v. Jones*, 2009 WL 4730305, at *29, *30 (W.D. Tex. Dec. 4, 2009) (noting that "adjudication of the County's state-law conspiracy to commit fraud claim requires factual determinations similar to those underlying the County's federal claims; namely, whether Defendants intended to defraud the County of its property"). There is accordingly no justification for dismissing Relators' state law claims.[13]

E. Relators Do Not Premise the Claims on Time-Barred Violations

Defendants point out that there is a six-year limitation period for FCA violations. Accordingly, Relators "are barred from claiming any FCA violation based on claims submitted before June 19, 2011." MTD at 35. This issue is premature, as Relators have not given any indication that they intend to pursue claims for FCA violations outside of the range of the six-year limitation period. Defendants' speculation – which is unsupported by anything contained in the AC – that Relators' claims may at some point breach the statute of limitations is not a justification to dismiss Relators' claims. Furthermore, the existence of a statute of limitations bar is an affirmative defense. "A plaintiff typically is not required to plead, in the complaint, facts that negate an affirmative defense." *Jaso v. The Coca Cola Co.*, 435 Fed. App'x 346, 351 (5th Cir. 2011). Dismissal of a complaint on statute of limitations grounds is therefore inappropriate unless the facts alleged in a complaint foreclose all possible arguments against the defense. *Id*. at 352; *Matassarin v. Grosvenor*, 2015 WL 12734174, at *11 (W.D. Tex. Oct. 19, 2015), *report and recommendation adopted*, No. 5:13-CV-00913-RP, 2015 WL 12734175 (W.D.

[13] Defendants alternatively argue that if the Court dismisses Relators' Federal FCA claims, it should decline to exercise supplemental jurisdiction over the state law claims. MTD at 34 n. 14. The Court may, in its discretion, retain supplemental jurisdiction over state claims even if Relators' Federal claims are dismissed, if such action would further judicial economy and fairness. *See United States ex rel. Jackson v. Univ. of N. Tex.*, 673 Fed. App'x 384, 388 (5th Cir. 2016). In this instance, it is much more economical to litigate Respondents' state law claims at once instead of in fifty different state courts. This would also promote fairness because it would eliminate the inevitably inconsistent rulings and outcomes.

Tex. Dec. 8, 2015). The AC alleges that Defendants' schemes continued at least through 2015, and up to the present day. AC ¶¶ 184-204. Relators' claims are therefore not foreclosed by the statute of limitations and dismissal is inappropriate on these grounds.

F. The Addition of Relator Green in the AC Was Appropriate

Defendants' argument that Green should be dismissed from this action fails. To begin with, it is premised on a misapplication of the law. Defendants cite to the first-to-file rule to block the addition of Green. But that rule simply states that a new action cannot be initiated if it arises out of the same allegations as those disclosed in a prior and pending action. Relators, however, simply filed an amended complaint with an additional relator. The first-to-file rule does not apply in such circumstances. *See United States ex rel. Fisher v. Ocwen Loan Servicing, LLC*, 2016 WL 3031713, at *1 (E.D. Tex. May 25, 2016) (adding relator after complaint unsealed did not implicate first-to-file rule); *United States v. Homeward Residential, Inc.*, 2015 WL 3776478, at *4 (E.D. Tex. June 17, 2015) (agreeing with 10th Circuit rule that "the first-to-file bar does not apply to a second relator who was voluntarily added to an existing complaint, because voluntarily adding a relator is not an intervention within the meaning of Rule 24" and the additional relator "does not bring a later and separate 'related action' under § 3730(b)(5) when he or she joins an existing action through an amended complaint"); *United States ex rel. Kaczmarcyk v. SCCI Health Servs. Corp.*, 2004 WL 7089810, at *1 (S.D. Tex. Mar. 11, 2004) (no first-to-file problem when relators added two additional former employees as relators in their amended complaint). Defendants' cited cases, which all address subsequent complaints filed in entirely different actions, do not hold otherwise.[14]

[14] *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 375 (5th Cir. 2009) (barring a complaint alleging similar facts in an action unconnected to an earlier-filed case); *United States ex rel. Denenea v. Allstate Ins. Co.*, 2011 WL 231780, at *2 (E.D. La. Jan.

In any event, the addition of Green as a relator is not a "consolidation [of her] claim with an earlier action," nor is she an "opportunistic successive plaintiff," as in the cases cited by Defendants. MTD at 37 (citing *Denenea*, 2011 WL 231780, at *1; *Lujan*, 243 F.3d at 1187). Indeed, Green was one of the confidential informants who worked with Relators to initiate this action and she was one of the confidential informants quoted in the original complaint. Defendants have not identified any law prohibiting an individual who was involved in this action from the inception from being added as a relator.

24, 2011) (same); *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1184 (9th Cir. 2001) (same).

V. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss should be denied.

Dated: March 26, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on March 26, 2018 to counsel of record who are deemed to have consented to electronic services via the Court's CM/ECF system. Any other counsel of record will be served by electronic mail, facsimile, U.S. Mail and/or overnight delivery.

/s/ Radu A Lelutiu
Radu Lelutiu